

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ORTHOLOGIC CORP.**

I. PREAMBLE

OrthoLogic Corp. hereby agrees to enter into this Corporate Integrity Agreement (the "CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") in an effort to ensure compliance with the requirements of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) by OrthoLogic, its directors, officers, employees, as well as all third parties with whom OrthoLogic may choose to engage to act as agents or consultants. On or about this date, OrthoLogic is entering into a settlement agreement with the United States and this CIA is incorporated by reference into that settlement agreement.

II. TERM OF THE AGREEMENT

The period of the compliance obligations assumed by OrthoLogic under this CIA shall be three (3) years from the date of execution of this CIA (unless otherwise specified).

III. CORPORATE INTEGRITY OBLIGATIONS

a. Policies and Notice. Within 90 days of the execution of this CIA, OrthoLogic will adopt and implement policies, procedures and practices designed to ensure compliance with the requirements of Medicare, Medicaid and all other federal health care programs for marketing of and billing for medical devices. In addition, OrthoLogic shall post in a prominent place accessible to each employee a notice detailing its commitment to comply with all applicable statutes, regulations and directives applicable to Medicare, Medicaid and all other federal health care programs in the conduct of its business.

b. Training and Education.

(1) *General Training.* Within 90 days of the execution of this CIA, OrthoLogic will develop and institute an information and education program designed to ensure that each officer, director, and employee who has any responsibility for activities related to the marketing of or billing for medical devices to Federal health care programs or their beneficiaries (hereinafter referred to as "Supplier Employees") is aware of: (1) all statutes, regulations, policies, procedures, and guidelines related to Medicare, Medicaid, and other federal health care program and applicable to the marketing of or billing for the types of medical devices sold by OrthoLogic; (2) OrthoLogic's policies, procedures and practices (described in section III.a) and; (3) the standards of business conduct that such an individual is expected to follow and the consequences both to the individual and OrthoLogic that will ensue from any violation of the requirements. Pursuant to this

program, each officer, director and employee who has any responsibility for activities related to the marketing of or billing for medical devices shall receive at least one hour of general training regarding these subjects. The following categories of Supplier Employees shall receive such general training within 90 days of the execution of this CIA: billing department personnel, and all senior management who work at OrthoLogic's headquarters in Tempe, Arizona. Subsequently, new Supplier Employees who fall within the above-described categories shall receive such training within two weeks of beginning employment. All Supplier Employees who do not fall within the above-described categories shall receive this general training by January 31, 1999. Subsequently, such new Supplier Employees shall receive this general training within 30 days of beginning employment.

(2) *Specific Training.* Independent from and in addition to the general training described above, OrthoLogic shall also implement a specific training program for all employees or contractors involved in directly involved in formulating, determining, or implementing policies for the marketing of or billing for medical devices to Federal health care programs or their beneficiaries. This program shall provide for no less than three hours of formal training on an annual basis for the next three years on the statutes, regulations, and program requirements of Medicare, Medicaid, and other federal health care programs related to the marketing of or billing for the types of medical devices marketed by or billed for by OrthoLogic. The initial specific training should be provided

by the later of: (1) 90 days after the execution of this CIA; or (2) two weeks after an employee or contractor assumes any responsibility for determining or implementing policies for the marketing of or billing for medical devices.

c. Review and Disclosure.

(1) *Review of Practices.* For three years from the effective date of this CIA, OrthoLogic will have an experienced attorney with knowledge of the federal health care statutes, regulations, policies, procedures, and guidelines, including those issued by the Health Care Financing Administration (HCFA) and its contractors: (i) review any proposed changes to OrthoLogic's policies and procedures related to the marketing of or billing for medical devices to federal health care programs or their beneficiaries prior to any implementation of such changes by OrthoLogic, and (ii) annually review all of OrthoLogic's practices related to the marketing of or billing for medical devices to federal health care programs or their beneficiaries. Although the review may be subject to the attorney-client privilege, the underlying OrthoLogic documents used in the reviews described in this section shall be maintained and available for OIG review and inspection for a minimum of four years.

(2) *Disclosure of Material Deficiencies.* If, during these reviews or through any other means, OrthoLogic discovers a material deficiency related to the marketing of or billing for medical devices to federal health care programs or their beneficiaries, OrthoLogic shall report to the OIG within a reasonable period of time, which shall not be

later than 60 days after determining that there is credible evidence of a material deficiency. The report shall include: (i) OrthoLogic's findings concerning the material deficiency; (ii) OrthoLogic's actions to correct such material deficiency; and (iii) any further steps OrthoLogic plans to take to address such material deficiency and prevent it from reoccurring. For purposes of this CIA, a "material deficiency" shall mean any act or omission that has a significant, adverse financial impact upon Medicare, Medicaid or any other federal health care programs, which may be the result of an isolated event or a series of occurrences, and which lacks conformity with Medicare, Medicaid or any other federal health care programs coverage or reimbursement principles or other applicable statutes, the regulations and written directives issued by HCFA and/or its agents, or any other agency charged with administering the health care program implicated and/or its agents.

d. Excluded Individuals. Effective upon the date of execution of this CIA, OrthoLogic shall not employ, contract with, or otherwise use the services of any individual whom OrthoLogic knows or should have known, after reasonable inquiry, (a) has been convicted of a criminal offense related to health care (unless the individual has been reinstated to participation in Medicare after being excluded because of the conviction), or (b) is currently listed by a federal agency as excluded, debarred, or otherwise ineligible for participation in any Federal health care program. In furtherance of this requirement, OrthoLogic agrees to make reasonable inquiry as to any individual

who is a prospective Supplier Employee, or individual considered for engagement by OrthoLogic as an independent contractor to be involved in the marketing of or billing for medical devices to Federal health care programs or their beneficiaries by reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available over the internet at <http://www.arnet.gov/epls>) and the HHS/OIG Cumulative Sanction Report (available over the internet at <http://www.dhhs.gov/progorg/oig>).

IV . OIG INSPECTION, AUDIT AND REVIEW RIGHTS. In addition to any other right the OIG may have by statute, regulation, or other authority, the OIG or its duly authorized representative(s) may examine OrthoLogic's books, records, and other company documents and supporting materials for the purpose of verifying and evaluating: (i) OrthoLogic's compliance with the terms of this CIA; and (ii) OrthoLogic's compliance with the requirements of the Medicare, Medicaid and other federal health care programs. The documentation described above shall be made available by OrthoLogic at all reasonable times for inspection, audit, and reproduction. Furthermore, for purposes of this provision, OIG or its authorized representative(s) may interview any of OrthoLogic's Supplier Employees who consent to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee and OIG for any of the purposes set forth above. OrthoLogic agrees to assist OIG in contacting and arranging interviews with such employees upon OIG's request. Such employees shall have the right to have counsel present during such

interviews and the right to be interviewed without any OrthoLogic representative or counsel being present.

V. **INITIAL AND ANNUAL REPORTS** OrthoLogic shall report to the OIG regarding its implementation of the requirements of this CIA.

a. **Interim Report** Within 120 days of the effective date of this CIA, OrthoLogic shall submit to OIG an interim report including: (i) a copy of the policies, procedures, practices and notice required under section III.a; and (ii) a report on the development and institution of the information and education program required under section III.b.

b. **Annual Reports** Within 30 days of the first, second, and third anniversary dates of the execution of this CIA, OrthoLogic shall provide an annual report including: (i) any changes in the policies, procedures, and notice required under section III.a since the most recent preceding report; (ii) any changes in the information and education program required under section III.b since the most recent preceding report; (iii) a certification from an officer of OrthoLogic that an attorney has conducted the review required in section III.c; and (iv) a certification from an officer of OrthoLogic that the training requirements of III.b have been fulfilled.

VI. **NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated subsequent to the execution of this CIA, all notifications and reports required under the terms of this CIA shall be submitted to the entities listed below:

If to the OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

If to Orthologic:

Ruben Chairez, Ph.D.
Vice President of Medical, Regulatory and
Clinical Affairs & Compliance Officer
OrthoLogic Corp.
1275 West Washington
Tempe, AZ 85282
Phone 602.286.5507
Fax 602.470.7080

VI. PRIVILEGES AND DISCLOSURES

Nothing in this CIA shall constitute a waiver of the attorney-client privilege or the attorney work product doctrine, or shall require OrthoLogic to waive such privileges and protections. Subject to HHS's Freedom of Information Regulations, set forth in 45 C.F.R. part 5, the OIG shall make a reasonable effort to notify OrthoLogic prior to any release by the OIG of information submitted by OrthoLogic pursuant to its obligations under this CIA and identified upon submission as trade secrets or privileged or confidential

commercial or financial information within the meaning of the Freedom of Information Act (FOIA), 5 U.S.C. § 552(b)(4), and HHS's Freedom of Information Regulations, 45 C.F.R. § 5.65. OrthoLogic will refrain from identifying any information as trade secrets or privileged or confidential commercial or financial information unless the information meets the criteria for exemption from disclosure under FOIA and HHS's Freedom of Information Regulations.

VII. DOCUMENT AND RECORD RETENTION

OrthoLogic shall maintain for inspection documents and records relating to reimbursement from the federal health care programs or with compliance with this CIA until the fourth anniversary of the execution of this CIA or until otherwise required to retain such records, whichever is later.

VIII. BREACH AND DEFAULT PROVISIONS

OrthoLogic's compliance with the terms and conditions in this CIA shall constitute an element of OrthoLogic's present responsibility with regard to participation in Federal health care programs. Full and timely compliance by OrthoLogic shall be expected throughout the duration of the compliance period required by this CIA with respect to all of the obligations herein agreed to by OrthoLogic. All modifications to this CIA (including changes to dates on which an obligation is due to be met) shall be requested in writing and agreed to by the OIG in writing prior to the date on which the modification is expected to take effect.

a. Stipulated Penalties for Failure to Comply with Corporate Integrity Obligations.

As a contractual remedy, OrthoLogic and OIG hereby agree that failure to comply with the obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “stipulated penalties”).

(1) A stipulated penalty of \$1,500 (which shall begin to accrue on the date the obligation became due) for each day OrthoLogic fails to have in place any of the following during the entire period beginning 90 days after the execution of this CIA and concluding at the end of the corporate integrity period required by this CIA:

- a. written Policies and Procedures;
- b. a training and education program;
- c. a mechanism for obtaining a legal review of its practices;
- d. a mechanism for reporting material deficiencies;

(2) A stipulated penalty of \$1,500 (which shall begin to accrue on the date the obligation became due) for each day OrthoLogic fails meet the deadline set forth in section V to provide a written interim report within 120 days of the execution of this CIA and submission of annual written annual reports within 30 days of the first, second, and third anniversary dates of the execution of this CIA.

(3) A stipulated penalty of \$1,500 (which shall begin to accrue on the date the failure to comply began) for each day OrthoLogic employs or contracts with an individual after that individual has been listed by a federal agency as excluded, debarred,

suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)). This stipulated penalty shall not be demanded if OrthoLogic can demonstrate that it did not discover the individual's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.d) as to the current or potential status of the employee or consultant engaged.

(4) A stipulated penalty of \$1,000 (which shall begin to accrue on the date that the OIG provides notice to OrthoLogic of the failure to comply) for each day OrthoLogic fails to comply with any corporate integrity requirement in this CIA where the failure to comply does not form the basis for stipulated penalties under provisions (1), (2), or (3) above.

b. Payment of Stipulated Penalties.

(1) *Demand Letter.* Upon finding that OrthoLogic has failed to comply with any of the corporate integrity obligations in this CIA and determining that stipulated penalties are appropriate, the OIG shall notify OrthoLogic by certified mail of: (i) OrthoLogic's failure to comply; and (ii) the OIG's exercise of its contractual right to demand payment of the stipulated penalties (this notification is hereinafter referred to as the "Demand Letter"). Within ten days of its receipt of the Demand Letter, OrthoLogic shall either: (i) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; (ii) request a hearing before an HHS administrative law judge (ALJ) to dispute

the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below; or (iii) be in material breach of this CIA. OrthoLogic's election of the contractual right to seek ALJ review of OIG's noncompliance determination shall not preclude OrthoLogic from also choosing to pay the applicable stipulated penalties at any time after receiving the Demand Letter.

(2) *Timely Written Requests for Extensions.* OrthoLogic may submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request, stipulated penalties shall not begin to accrue unless and until OrthoLogic fails to meet the deadline granted by the extension.

Notwithstanding any other provision in this section, if OIG denies a timely written request, stipulated penalties shall not begin to accrue until two business days following OrthoLogic's receipt of OIG's written denial of such a timely written request. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which the act is due to be performed or notification or report is due to be filed.

(3) *Form of Payment.* Payment of the stipulated penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to the OIG at the address set forth above.

(4) *Independence from Material Breach Determination.* Except as otherwise noted, these provisions for payment of stipulated penalties shall not affect or otherwise set a standard for the OIG's determination that OrthoLogic has materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions set forth below.

c. Exclusion for Material Breach.

(1) *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by OrthoLogic constitutes an independent basis for OrthoLogic's exclusion from participation in Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by the OIG that OrthoLogic has materially breached this CIA and that exclusion should be imposed, the OIG shall notify OrthoLogic by certified mail of: (i) OrthoLogic's material breach; and (ii) the OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude Letter").

(2) *Opportunity to Cure.* OrthoLogic shall have 30 days from its receipt of the Notice of Material Breach and Intent to Exclude Letter to proceed as follows:

- (i) demonstrate to the OIG's satisfaction that OrthoLogic has not committed a material breach of this CIA;
- (ii) cure the alleged material breach; or

- (iii) demonstrate to the OIG's satisfaction that the alleged material breach cannot be cured within the 30-day period, but that (i) OrthoLogic has begun to take action to cure the material breach, (ii) OrthoLogic is pursuing such action with due diligence, and (iii) OrthoLogic has provided to the OIG a reasonable timetable for curing the material breach.

(3) *Exclusion Letter.* If at the conclusion of the 30-day period (or other specific period as subsequently agreed by OIG and OrthoLogic), OrthoLogic fails to meet the requirements of section VIII.c(2) above, OIG may exclude OrthoLogic from participation in the Medicare, Medicaid and any other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). OIG will notify OrthoLogic in writing of its determination to exclude OrthoLogic (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the dispute resolution provisions in section VIII.d, the exclusion shall go into effect 20 days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If OrthoLogic is excluded under the provisions of this CIA, OrthoLogic may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

(4) *Material Breach.* A material breach of this CIA means: (i) a failure by OrthoLogic to meet an obligation under this CIA where the failure has a significant

adverse impact on the integrity of Medicare, Medicaid, or any other Federal health care program (for example, a failure to report credible evidence of a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.c); (ii) repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section VIII.a; or (iii) failure to either pay stipulated penalties or request a hearing by an ALJ as required by VIII.b.

d. Dispute Resolution.

(1) *Review Rights.* Upon the OIG's delivery to OrthoLogic of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, OrthoLogic shall be afforded some review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005 as if they applied to the stipulated penalties or exclusion sought pursuant to this CIA. Specifically, the OIG's determination to demand payment of stipulated penalties or to seek exclusion shall be subject to review by an HHS administrative law judge (ALJ) in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving stipulated penalties shall be made within 10 days of OrthoLogic's receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of its receipt of the Exclusion Letter.

(2) *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for stipulated penalties under this CIA shall be: (i) whether OrthoLogic was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and, (ii) the period of noncompliance. OrthoLogic shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. For purposes of paying stipulated penalties under this CIA, and if OrthoLogic chooses to seek review in lieu of curing the breach and paying the stipulated penalties, as set forth above, the ALJ's decision (if in favor of the OIG) shall trigger OrthoLogic's obligation to pay. Thus, payment will be due 20 days after the date that the ALJ issues the decision.

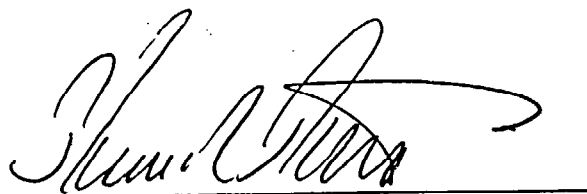
(3) *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a breach of this CIA shall be: (i) whether OrthoLogic was in material breach of this CIA; and (ii) whether such breach was continuing on the date of the Exclusion Letter. For purposes of the exclusion herein agreed to in the event of material breach of this CIA, the ALJ's decision shall trigger the exclusion. Thus, the OIG may proceed with its exclusion of OrthoLogic if and when the ALJ issues a decision in favor of the OIG.

IX. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the settlement agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, OrthoLogic and the OIG agree as follows:

1. this CIA shall be binding on the successors, assigns and transferees of OrthoLogic;
2. this CIA shall become final and binding upon signing by each respective party hereto;
3. any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and
4. the undersigned OrthoLogic signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF ORTHOLOGIC



THOMAS R. TROTTER
President and CEO
OrthoLogic Corp.

8/11/98
DATE



for LYNN SHAPIRO SNYDER
Epstein Becker & Green, P.C.
Counsel to OrthoLogic Corp.

8/12/98
DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES



LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

8/19/98
DATE